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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR      | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|---------------------------|---------------------|------------------|
| 09/914,257  | 01/07/2002  | Carlos Manucl Miyares Cao | LEXSA.P0024         | 2224             |
| 28752   | 7590        | 04/21/2004                | EXAMINER            |                  |
| LACKENBACH SIEGEL, LLP<br>LACKENBACH SIEGEL BUILDING<br>1 CHASE ROAD<br>SCARSDALE, NY 10583 |             |                           | WITZ, JEAN C        |                  |
|   |             | ART UNIT                  | PAPER NUMBER        |                  |
|   |             | 1651                      |                     |                  |

DATE MAILED: 04/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                          |                               |
|------------------------------|--------------------------|-------------------------------|
| <b>Office Action Summary</b> | Application No.          | Applicant(s)                  |
|                              | 09/914,257               | MIYARES CAO, CARLOS<br>MANUEL |
|                              | Examiner<br>Jean C. Witz | Art Unit<br>1651              |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 19 December 2003.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 5-9 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 5-9 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date, \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_.

## DETAILED ACTION

### ***Response to Arguments***

1. Applicant's arguments with respect to claims 5-9 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 112***

2. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites fatty acid components of the composition as "arachinoidic" and "eicosietienoic" acids. These terms do not appear in the prior art. It may be that these terms are misspelled and should read "arachidonic" and "eicosatrienoic". However, since many fatty acid names are similarly spelled, the spellings of these terms render the claims vague and indefinite because the metes and bounds of the claimed composition is not clear.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over FR 0298787 combined with U.S. Patent 5,612,052 to Shalaby in view of WO 9010441, WO 9507091, U.S. Patent 6,150,326 to Golovistokiv et al., and SU 1061818.

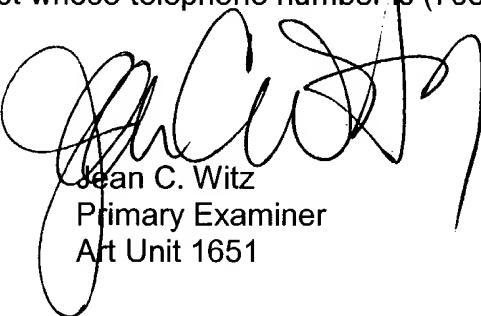
FR 0298787 discloses an alcoholic extract of placental tissues and discloses that this extract contains multiple types of polyunsaturated fatty acids including all fatty acids recited in claim 5. SU 1061818 teaches that placental suspensions are known for treating psoriasis. U.S. Patent 6,150,326 to Golovistokiv et al. reiterates this teaching. WO 9010441 teaches that polyunsaturated fatty acids such as those claimed, including palmitoleic, linoleic and oleic acids are known and useful for the treatment of psoriasis. Similarly, WO 9507091 teach that oleic acid or linoleic acid in combination with n-3 or n-6 fatty acids are useful in the treatment of psoriasis. Finally, Shalaby teaches that a hydrogel may be conventionally used to formulate topical compositions for treatment of conditions of the skin.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to formulate the extract of FR 0298787 for the topical treatment of psoriasis since it is known that the contents of said extract will be appropriate for the treatment psoriasis. Further, it is deemed conventional and well within the skill of one of ordinary skill in the art to formulate a composition for topical administration as a hydrogel for the benefits of providing a protective barrier and controlled release of the active ingredient. Absent objective evidence to the contrary, optimization of dose is deemed well within the skill of the practitioner.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jean C. Witz whose telephone number is (703) 308-3073. The examiner can normally be reached on 6:30 a.m. to 4:00 p.m. M-Th and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (703) 308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Jean C. Witz  
Primary Examiner  
Art Unit 1651

April 18, 2004